particles have an average particle size of less than about 1000 nm when measured by light scattering techniques;

(b) at least one surface stabilizer associated with the surface of the nanoparticulate drug, and

(c) at least one pharmaceutically acceptable rate-controlling polymer,

wherein the composition provides controlled release of the nanoparticulate drug for a time period ranging from about 2 to about 24 hours.

2. (Amended) The composition of claim 1, wherein the effective average particle size of the nanoparticulate drug is selected from the group consisting of less than about 800 nm, less than about 600 nm, less than about 400 nm, less than about 300 nm, less than about 250 nm, less than about 100 nm, and less than about 50 nm, wherein at least 50% of the drug particles have an average particle size of less than about 800, 600, 400, 300, 250, 100, or 50 nm, respectively, when measured by light scattering techniques.

9. (Amended) The composition of claim 1 formed by wet granulation, wherein water is added to the nanoparticulate drug, surface stabilizer, and polymer to form granules prior to forming the solid dose of the controlled release formulation.

13. (Amended) The composition of claim 1, wherein the poorly water soluble nanoparticulate drug is present in an amount of from about 1 μg to about 800 mg.

15. (Amended) The dosage form of claim 14, wherein the nanoparticulate drug and at least one auxiliary excipient are compressed into tablet form prior to coating with a rate controlling polymer.

16. (Amended) The dosage form of claim 14, wherein the nanoparticulate drug, the rate controlling polymer and at least one auxiliary excipient are compressed to form a controlled release matrix tablet.

18. (Amended) The dosage form of claim 14, wherein the nanoparticulate drug and at least one auxiliary excipient are compressed into the form of a multilayer tablet prior to coating with a rate controlling polymer.

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19. (Amended) The dosage form of claim 14, wherein the nanoparticulate drug is dispersed in the rate controlling polymer material and compressed into the form of a multilayer tablet.

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21. (Amended) The dosage form according to claim 14, wherein the nanoparticulate drug, at least one auxiliary excipient, and the rate controlling polymer material are combined into a multiparticulate form.

30. (Amended) A method of preparing a solid dose controlled release nanoparticulate formulation comprising:

(a) combining a nanoparticulate composition of a nanoparticulate drug to be administered and at least one surface stabilizer associated with the surface of the nanoparticulate drug, wherein the composition has an effective average particle size of less than about 1000 nm, wherein at least 50% of the drug particles have an average particle size of less than about 1000 nm when measured by light scattering techniques, and at least one suitable rate-controlling polymer; and

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(b) forming a solid dose of the mixture from step (a), wherein the solid dose formulation has a controlled release of the nanoparticulate drug following administration for a time period ranging from about 2 to about 24 hours.

31. (Amended) The method of claim 30, wherein the effective average particle size of the nanoparticulate drug particles is selected from the group consisting of less than about 800 nm, less than about 600 nm, less than about 400 nm, less than about 300 nm, less than about 250 nm, less than about 100 nm, and less than about 50 nm , wherein at least 50% of the drug particles have an average particle size of less than about

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800, 600, 400, 300, 250, 100, or 50 nm, respectively, when measured by light scattering techniques.

34. (Amended) The method of claim 31, comprising adding water to the nanoparticulate drug, surface stabilizer, and rate-controlling polymer to form granules prior to step (b).

35. (Amended) A method of treating a mammal comprising administering to the mammal an effective amount of a solid dose controlled release nanoparticulate formulation wherein:

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(a) the formulation comprises nanoparticulate drug particles to be administered and at least one surface stabilizer associated with the surface of the nanoparticulate drug, wherein the nanoparticulate drug particles have an effective average particle size of less than about 1000 nm, wherein at least 50% of the drug particles have an average particle size of less than about 1000 nm when measured by light scattering techniques, and at least one suitable rate-controlling polymer; and

(b) the formulation has a controlled release of the nanoparticulate drug following administration for a time period ranging from about 2 to about 24 hours.

Please add the following new claim.

36. (New) The method of claim 35, wherein the effective average particle size of the nanoparticulate drug particles is selected from the group consisting of less than about 800 nm, less than about 600 nm, less than about 400 nm, less than about 300 nm, less than about 250 nm, less than about 100 nm, and less than about 50 nm, wherein at least 50% of the drug particles have an average particle size of less than about 800, 600, 400, 300, 250, 100, or 50 nm, respectively, when measured by light scattering techniques.

REMARKS

Applicants respectfully request reconsideration of this application.